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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/087,449

Applicant(s)

BLOMQUIST, MICHAEL L.

Examiner

Jennifer L. Norton

Art Unit

2121

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-25 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
4) ☐ Interview Summary (PTO-413)
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____
Paper No(s)/Mail Date _____

DETAILED ACTION

1. The following is a **Final Office Action** in response to the Amendment received on 15 September 2008. Claims 1, 8 and 9 have been amended. Claims 1-25 are pending in this application.

Claim Objections

2. Claims 1 and 12 are objected to because of the following informalities:

- Claim 1, line 4 includes the grammatical error "a user-interface".
- Claim 12, line 2 includes the grammatical error "a user".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 12-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent Publication No. 2003/0114836 (hereinafter Estes).

5. As per claim 12, Estes discloses a method of operating an infusion pump (Fig. 1, element 100) for delivering a therapeutic agent into the body of a user (pg. 3, par. [0029]), the infusion pump being programmable (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132) and including memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the infusion pump being programmed to run a delivery program (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (pg. 3, par. [0032]-[0034], pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY), the method comprising:

storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM);

selecting the uniquely identifying name thereby assigning the set of operating parameters identified by the uniquely identifying name to the delivery program (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

running the delivery program (pg. 8, par. [0073] and Fig. 6), the delivery program executing the set of operating parameters thereby controlling the infusion

pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (pg. 6, par. [0057] and [0059]).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "selecting the uniquely identifying name thereby assigning the set of operating parameters identified by the uniquely identifying name to the delivery program" as follows:

Claim 12 is rejected under 35 U.S.C. 102(e) as anticipated by Estes or, in the alternative, under 35 U.S.C. 103(a) as obvious over Estes in view of U.S. Patent No. 2003/0011646 (hereinafter Levine).

As per claim 12, Estes teaches a method of operating an infusion pump (Fig. 1, element 100) for delivering a therapeutic agent into the body of a user (pg. 3, par. [0029]), the infusion pump being programmable (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132) and including memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the infusion pump being programmed to run a delivery program (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (pg. 3, par. [0032]-[0034], pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY), the method comprising:

storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg.

6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

running the delivery program (pg. 8, par. [0073] and Fig. 6), the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (pg. 6, par. [0057] and [0059]).

Estes teaches to a method substantially the same as claimed but does not expressly teach selecting one unique identifying Name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

Levine teaches selecting the uniquely identifying name (Fig. 23, i.e. "Medication" type) thereby assigning the set of operating parameters identified by the uniquely identifying name to the delivery program (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include selecting the uniquely identifying name thereby assigning the set of operating parameters identified

by the uniquely identifying name to the delivery program to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

6. As per claim 13, Estes discloses downloading the data set to the pump from a computer (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

7. As per claim 14, Estes discloses storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), includes storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

8. As per claim 15, Estes discloses generating a menu, the menu including at least one menu item corresponding to one of the unique identifying names; and wherein

selecting the unique identifying name includes selecting the menu item (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

9. As per claim 16, Estes discloses wherein storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), includes storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

10. As per claim 17, Estes discloses generating a menu includes generating a menu having at least one menu item corresponding to a unique identifying name from one data set and at least one menu item corresponding to a unique identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

11. As per claim 18, Estes discloses the execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

12. As per claim 19, Estes discloses an infusion pump (pgs. 2-3, par. [0027] and Fig. 1, element 100) comprising:

a pump mechanism (pg. 3, par. [0029]);

memory storing a data set (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

a processor (pg. 3, par. [0034]; e.g. PC, laptop) arranged to control the pump mechanism and in data communication with the memory (pgs. 3-4, par. [0034]), the processor being programmed to assign the set of operating parameters (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program upon selection of the uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM) and to execute the set of operating parameters thereby controlling the pump

mechanism to deliver the therapeutic agent according to the delivery schedule (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach the "the delivery program upon selection of the uniquely identifying name" as follows:

Claim 19 is rejected under 35 U.S.C. 102(e) as anticipated by Estes or, in the alternative, under 35 U.S.C. 103(a) as obvious over Estes in view of Levine.

As per claim 19, Estes teaches an infusion pump (pgs. 2-3, par. [0027] and Fig. 1, element 100) comprising:

- a pump mechanism (pg. 3, par. [0029]);

- memory storing a data set (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

- a processor (pg. 3, par. [0034]; e.g. PC, laptop) arranged to control the pump mechanism and in data communication with the memory (pgs. 3-4, par. [0034]), the processor being programmed to assign the set of operating parameters (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time

Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY) and to execute the set of operating parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes teaches to a method substantially the same as claimed but does not expressly teach the delivery program upon selection of the uniquely identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Levine teaches the delivery program upon selection of the uniquely identifying name (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23, i.e. "Medication" type).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include the delivery program upon selection of the uniquely identifying name to the delivery program to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

13. As per claim 20, Estes discloses a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop), the processor being further arranged to control downloading of the data set and storage of the data set into the memory (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

14. As per claim 21, Estes discloses the memory stores two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

15. As per claim 22, Estes discloses the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, wherein selecting the menu item is at least one step in beginning execution of the delivery program (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

16. As per claim 23, Estes discloses the memory stores two or more data sets (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time

change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

17. As per claim 24, Estes discloses the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to a unique identifying name from one data set and at least one unique identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

18. As per claim 25, Estes discloses the processor is further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 1-11, 13-18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of Levine.

21. As per claim 1, Estes teaches a method of programming an ambulatory infusion pump (Fig. 1, element 100) from a computer (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the ambulatory infusion pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program being driven by operating parameters (pg. 3, par. [0032] and [0033]), the method comprising:

generating a table (Fig. 3A, element 300) on an interface displayed by the computer the computer having a computer peripheral (col. 6, par. [0054]), the table (Fig. 3A) containing a row, the row having a plurality of cells (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), and each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3); and
downloading the operating parameters into the pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes teaches a user-interface displayed (Fig. 3B-3D) by the computer the computer having a computer peripheral (pg. 6, par. [0056]) but does not expressly teach generating a table on a user-interface displayed by the computer the computer having a computer peripheral, entering receiving an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral.

Levine teaches to a user-interface (Fig. 23, element 1800) displayed by the computer (Fig. 3, element 120, 130 and 140) the computer having a computer peripheral (pg. 2, par. [0038], pgs. 4-5, par. [0090] and pg. 11, par. [0147]), entering receiving an operating parameter into at least one of the cells (Fig. 23, element 1812) in the table (pg. 11, par. [0147] and Fig. 23, element 1800), the operating parameter being entered directly into the at least one of the cells through the computer peripheral (pg. 11, par. [0147]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a table on a user-interface displayed by the computer the computer having a computer peripheral, entering receiving an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

22. As per claim 2, Estes teaches the table includes a plurality of rows (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Levine teaches each row relating to a different set of operating parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23), each set of operating parameters defining a different delivery schedule for the pump (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

23. As per claim 3, Estes teaches as set forth above at least one cell within each row is configured for a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "at least one cell within each row is configured for a unique identifying name, wherein the unique identifying name identifies the

operating parameters in the same row of as the unique identifying name” as follows:

Estes teaches to a method substantially the same as claimed but does not expressly teach one cell within each row is configured for a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Levine teaches one cell within each row is configured for a unique identifying name (Fig. 23, i.e. "Medication"), wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23)

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include one cell within each row is configured for a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

24. As per claim 4, Estes teaches as set forth above the pump has memory (Fig. 2, element 106) and runs a delivery program and downloading the operating parameters includes downloading the operating parameters into the pump includes downloading

the operating parameters into the memory (pgs. 3-4, par. [0035]; i.e. downloading the operating parameters from Fig. 2, element 132).

25. As per claim 5, Estes teaches as set forth above the pump is programmed to run a delivery program, the method further comprising running the delivery program, thereby executing the operating parameters (pg. 8, par. [0073] and Fig. 6).

26. As per claim 6, Estes teaches as set forth above the pump has memory (Fig. 2, element 106) and is programmed to run a delivery program (pgs. 3-4, par. [0035]; i.e. downloading the operating parameters from Fig. 2, element 132), the method further comprising:

downloading all rows of operating parameters to the infusion pump (pgs. 3-4, par. [0035] and Figs. 3A, element 300); and

storing the operating parameters in the memory (pgs. 3-4, par. [0035]).

27. As per claim 7, Estes teaches as set forth above selecting one unique identifying Name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "selecting one unique identifying and running

the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name” as follows:

Estes teaches to a method substantially the same as claimed but does not expressly teach above selecting one unique identifying Name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

Levine teaches selecting one unique identifying (Fig. 23, i.e. “Medication” type) and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant’s invention to modify the teaching of Estes to include selecting one unique identifying and running the delivery program wherein the delivery program executes the operating parameters identified by the selected unique identifying name to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

28. As per claim 8, Estes teaches a method of operating a pump (Fig. 1, element 100), the pump having a memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) and a pump mechanism (pg. 3, par. [0029]), the method comprising:

receiving from a computer, a plurality of data sets, each data set in the plurality of data sets containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage"),

storing the plurality of data sets in memory (pgs. 3-4, par. [0035] and Fig. 1, element 106);

selecting one of the plurality of data sets (pg. 8, par. [0008]) and Fig. 6, i.e. SUSPEND, BOLUS, BASAL); and

running a delivery program wherein the delivery program executes the operating parameters in the selected one of the plurality of data sets, the operating parameters defining a delivery schedule for controlling the pump mechanism (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes does not expressly teach wherein each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter.

Levine teaches each data set in the plurality of data sets contains the same type of operating parameters (Fig. 23, i.e. "Medication", "Date", "Dosage", "Frequency" and "Purpose of Medication") and at least two of the data sets contain different values for the same type of operating parameter (pg. 11, par. [0147] and Fig. 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

29. As per claim 9, Estes teaches an apparatus (Fig. 2, element 132) for programming an infusion pump (pgs. 2-3, par. [0027]), pgs. 3-4, par. [0034] and [0035] and Fig. 1, element 100), the pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program programmed to process operating parameters (pg. 3, par. [0032] and [0033]), the operating parameters defining operating of the pump (pg. 6, par. [0054]; i.e. corresponding operating parameters and

cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), the apparatus comprising:

- a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop);

- a data entry device (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop); and

- a processor in data communication with the data port and the data entry device (pg. 3, par. [0034]; e.g. PC, laptop),

generating a table (Fig. 3A, element 300), the table containing a row, the row having a plurality of cells (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3);

(b) receive data from the data entry device and display the data in one or more of the cells (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300); and

(c) download the operating parameters displayed (col. 6, par. [0054]) in the cells to the infusion pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes does not expressly teach the processor programmed to (a) generate a table.

Levine teaches the processor programmed to (a) generate a table (pg. 2, par. [0038], pgs. 4-5, par. [0090], pg. 11, par. [0147] and Fig. 23, element 1800).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include the processor programmed to (a) generate a table to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

30. As per claim 10, Estes teaches the processor is further programmed to generate a plurality of rows in the table rows (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Levine teaches to each row relating to a different set of operating parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23), each set of operating parameters defining a different delivery schedule for the pump (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row

relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

31. As per claim 11, Estes teaches as set forth above each row in the table includes at least one cell **configured to receive (as opposed to actually receiving)** a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "each row in the table includes at least one cell **configured to receive (as opposed to actually receiving)** a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name" as follows:

Estes teaches to a method substantially the same as claimed but does not expressly teach each row in the table includes at least one cell **configured to receive (as opposed to actually receiving)** a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Levine teaches each row in the table includes at least one cell **configured to receive (as opposed to actually receiving)** a unique identifying name (Fig. 23, i.e. "Medication"), wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23)

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row in the table includes at least one cell configured to receive a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (pg. 1, par. [0009]).

32. As per claim 13, Estes teaches as set forth above downloading the data set to the pump from a computer (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

33. As per claim 14, Estes teaches as set forth above storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), includes storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker

Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

34. As per claim 15, Estes teaches as set forth above to generating a menu, the menu including at least one menu item corresponding to one of the unique identifying names; and wherein selecting the unique identifying name includes selecting the menu item (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

35. As per claim 16, Estes teaches wherein storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), includes storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of

these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage”).

36. As per claim 17, Estes teaches as set forth above to generating a menu includes generating a menu having at least one menu item corresponding to a unique identifying name from one data set and at least one menu item corresponding to a unique identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element “Main Menu”).

37. As per claim 18, Estes teaches as set forth above to the execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

38. As per claim 20, Estes teaches set forth above a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop), the processor being further arranged to control downloading of the data set and storage of the data set into the memory (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

39. As per claim 21, Estes teaches as set forth above the memory stores two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A,

element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; [0064], lines 13-15, i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

40. As per claim 22, Estes teaches as set forth above the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, wherein selecting the menu item is at least one step in beginning execution of the delivery program (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

41. As per claim 23, Estes teaches as set forth above the memory stores two or more data sets (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's

settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

42. As per claim 24, Estes teaches as set forth above the processor is further programmed to generate a menu, the menu including at least one menu item corresponding to a unique identifying name from one data set and at least one unique identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

43. As per claim 25, Estes teaches as set forth above the processor is further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

Response to Arguments

44. Applicant's arguments see Remarks pgs. 8-11, filed 15 September 2008 with respect to claims 1-25 under 35 U.S.C. 102(e) have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references are cited to further show the state of the art with respect to medical management systems.

U.S. Patent Publication No. 2004/0167465 discloses a method and system for medical device authentication

U.S. Patent No. 2008/0300534 discloses an apparatus for indicating a change in operation of a medical infusion pump.

U.S. Patent No. 2008/0033402 discloses an apparatus comprising a pump configured to deliver insulin, an input configured to receive blood glucose data, a user interface, and a controller communicatively coupled to the pump, the input, and the user interface.

U.S. Patent No. 5,153,827 discloses an infusion management and pumping system having an alarm handling system.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer L. Norton whose telephone number is (571)272-3694. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert Decady can be reached on 571-272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Albert DeCady/
Supervisory Patent Examiner
Art Unit 2121